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भारतीय मानक

चिकित्सीय विद्युत उपस्कर

भाग 2 सुरक्षा के लिए विशिष्ट अपेक्षाएँ

अनुभाग 45 मामौग्राफी क्ष-किरण उपस्कर और मामौग्राफी स्टीरियोटैक्टिक उपकरण

Indian Standard

MEDICAL ELECTRICAL EQUIPMENT

PART 2 PARTICULAR REQUIREMENTS FOR THE SAFETY

Section 45 Mammographic X-Ray Equipment and Mammographic Stereotactic Devices

ICS 11.040.50

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BUREAU OF INDIAN STANDARDS
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NEW DELHI 110002

November 2007 **Price Group 12**

Electromedical Equipment Sectional Committee, MHR 15

NATIONAL FOREWORD

This Indian Standard (Part 2/Sec 45) which is identical with IEC 60601-2-45 : 2001 'Medical electrical equipment — Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices' issued by the International Electrotechnical Commission (IEC) was adopted by the Bureau of Indian Standards on the recommendation of the Electromedical Equipment Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

The text of IEC Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

b) Comma (,) has been used as a decimal marker, while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards, which are to be substituted in their respective places, are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 497 : 1973 Guide to the choice of series of preferred numbers and of series containing more rounded values of preferred numbers	IS 1076 (Part 3) : 1985 Preferred numbers: Part 3 Guide to the choice of series of preferred numbers and of series containing more rounded values of preferred number (*second revision*)	Identical
IEC 60601-1 : 1988[1] Medical electrical equipment — Part 1: General requirements for safety	IS 13450 (Part 1) : 1994 Medical electrical equipment: Part 1 General requirements for safety	do
IEC/TR 60788 : 2004 Medical electrical equipment — Glossary	IS 13807 : 1994 Medical radiology — Terminology	Technically Equivalent

The technical committee responsible for the preparation of this standard has reviewed the provisions of the following International Standards referred in this adopted standard and has decided that they are acceptable for use in conjunction with this standard:

International Standard	*Title*
IEC 60601-2-28 : 1993	Medical electrical equipment — Part 2-28: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis
IEC 61223-3-2 : 1996	Evaluation and routine testing in medical imaging departments — Part 3-2: Acceptance tests — Imaging performance of mammographic X-ray equipment

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[1] Since revised in 2005.

IS 13450 (Part 2/Sec 45) : 2007
IEC 60601-2-45 : 2001

Indian Standard
MEDICAL ELECTRICAL EQUIPMENT
PART 2 PARTICULAR REQUIREMENTS FOR THE SAFETY
Section 45 Mammographic X-Ray Equipment and Mammographic Stereotactic Devices

SECTION 1: GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

1.1 Scope

Addition:

This Particular Standard contains requirements for the safety of X-RAY EQUIPMENT designed for mammography and MAMMOGRAPHIC STEREOTACTIC DEVICES. The safety requirements for the X-RAY GENERATOR and its sub-assemblies form an integral part of this standard.

1.2 Object

Replacement:

The object of this standard is

1 to formulate appropriate design and manufacturing requirements for the safety of mammographic X-RAY EQUIPMENT and MAMMOGRAPHIC STEREOTACTIC DEVICES, reflecting the particular characteristics and circumstances of use of such equipment;

2 to establish particular requirements to ensure safety and to specify methods for demonstrating compliance with those requirements.

NOTE 1 Requirements for reproducibility, linearity, constancy and accuracy are given because of their relationship to the quality and quantity of the IONIZING RADIATION produced and are confined to those considered necessary for safety.

NOTE 2 Both the levels for compliance and the tests prescribed to determine compliance reflect the fact that the safety of HIGH-VOLTAGE GENERATORS is not sensitive to small differences in levels of performance. The combinations of LOADING FACTORS specified for the tests are therefore limited in number but chosen from experience as being appropriate in most cases. It is considered important to standardize the choice of combinations of LOADING FACTORS so that comparison can be made between tests performed in different places on different occasions. However, combinations other than those specified could be of equal technical validity.

NOTE 3 The safety philosophy on which this standard is based is described in the introduction to the General Standard and in IEC 60513.

NOTE 4 Concerning RADIOLOGICAL PROTECTION it has been assumed in the preparation of this standard that MANUFACTURERS and USERS do accept the general principles of the International Commission on Radiological Protection (ICRP) as stated in ICRP 60, 1990, paragraph 112,[1] namely:

"(a) No practice involving exposures to radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes. (The justification of a practice.)

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[1] ICRP Publication 60: *Recommendations of the International Commission on Radiological Protection (Annals of the ICRP Vol. 21 No 1-3, 1990)*. Published by Pergamon Press.

(b) In relation to any particular source within a practice, the magnitude of individual doses, the number of people exposed and the likelihood of incurring exposures where these are not certain to be received should all be kept as low as reasonably achievable, economic and social factors being taken into account. This procedure should be constrained by restrictions on the doses to individuals (dose constraints), or the risks to individuals in the case of potential exposures (risk constraints), so as to limit the inequity likely to result from the inherent economic and social judgements. (The optimisation of protection.)

(c) The exposure of individuals resulting from the combination of all the relevant practices should be subject to dose limits, or to some control of risk in the case of potential exposures. These are aimed at ensuring that no individual is exposed to radiation risks that are judged to be unacceptable from these practices in any normal circumstances. Not all sources are susceptible of control by action at the source and it is necessary to specify the sources to be included as relevant before selecting a dose limit. (Individual dose and risk limits.)"

NOTE 5 Most of the requirements on X-RAY EQUIPMENT and its sub-assemblies for protection against IONIZING RADIATION are given in the Collateral Standard IEC 60601-1-3.

This standard does, however, deal with some aspects of RADIOLOGICAL PROTECTION, mainly those that depend upon the supply, control and indication of electrical energy from the HIGH-VOLTAGE GENERATOR.

NOTE 6 It is recognized that many of the judgements necessary to follow the ICRP general principles have to be made by the USER and not by the MANUFACTURER of the EQUIPMENT.

1.3 Particular Standards

Addition:

This Particular Standard, hereinafter referred to as "this standard", amends and supplements a set of IEC publications, hereinafter referred to as "General Standard", consisting of IEC 60601-1: 1988, *Medical electrical equipment – Part 1: General requirements for safety*, its amendments 1 (1991) and 2 (1995) and all Collateral Standards.

The numbering of sections, clauses and subclauses of this standard corresponds to that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the General Standard is replaced completely by the text of this standard.

"Addition" means that the text of this standard is additional to the requirements of the General Standard.

"Amendment" means that the clause or subclause of the General Standard is amended as indicated by the text of this standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Where there is no corresponding section, clause or subclause in this standard, the section, clause or subclause of the General Standard applies without modification.

Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this standard.

A requirement of this standard replacing or modifying requirements of the General Standard takes precedence over the original requirements concerned.

1.3.101 Related International Standards

IEC 60601-2-28:1993, *Medical electrical equipment – Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis*

IEC 60664-1:1992, *Insulation coordination for equipment within low-voltage systems – Part 1: Principles, requirements and tests*

IEC 60788:1984, *Medical radiology – Terminology*

IEC 61223-3-2:1996, *Evaluation and routine testing in medical imaging departments – Part 3-2: Acceptance tests – Imaging performance of mammographic X-RAY EQUIPMENT*

ISO 497:1973, *Guide to the choice of series of preferred numbers and of series containing more rounded values of preferred numbers*

2 Terminology and definitions

This clause of the General Standard applies except as follows:

Associated conditions qualifying the usage of certain terms are given in 2.102.

a) In this standard unless otherwise indicated:
   - values of X-RAY TUBE VOLTAGE refer to peak values, transients being disregarded;
   - values of X-RAY TUBE CURRENT refer to average values.

b) The electric power in the high-voltage circuit mentioned in 6.8.2 a) 3) and 6.8.2 a) 4) is calculated according to the formula:

$$P = f\,U\,I$$

where

P is the electric power;

f is the factor depending on the waveform of the X-RAY TUBE VOLTAGE, selected as below and is:

   a) 0,95 for SIX-PEAK HIGH-VOLTAGE GENERATORS; or
   b) 1,00 for TWELVE-PEAK HIGH-VOLTAGE GENERATORS and CONSTANT POTENTIAL high-voltage generators; or
   c) for other HIGH-VOLTAGE GENERATORS, the most appropriate value, 0,95 or 1,00, chosen according to the waveform of the X-RAY TUBE VOLTAGE, with a statement of the value selected;

U is the X-RAY TUBE VOLTAGE;

I is the X-RAY TUBE CURRENT.

2.101 Additional Definitions

In this standard, terms printed in SMALL CAPITALS are used in accordance with their definitions either in the General Standard, in this standard, in IEC 60788 or in other IEC standards referenced in annex AA.

NOTE Attention is drawn to the fact that, in cases where the concept addressed is not strongly confined to the definition given in one of the publications listed above, a corresponding term is printed in lower case letters.

An index of defined terms used in this standard is given in annex AA.

For the purposes of this standard, the following additional definitions apply.

2.101.1 Not used.

2.101.2
MAMMOGRAPHIC STEREOTACTIC DEVICE
device for three-dimensional localization of a point within the breast, and for mechanically guided placement of a needle or position marker for such purposes as fine-needle aspiration, core biopsy and pre-surgical localization. The localization is based on radiographic images of an immobilized breast acquired at different known angles. Such a device may be a dedicated system or an ACCESSORY for mammographic X-RAY EQUIPMENT

2.101.3
CORE BIOPSY GUN
automatic needle device for performing core biopsy

2.101.4
DIRECT FOCAL DISTANCE
shortest distance from the X-RAY IMAGE RECEPTOR to the position of the FOCAL SPOT

2.102 Qualifying conditions for defined terms

2.102.1
operating conditions for NOMINAL X-RAY TUBE VOLTAGE
NOMINAL X-RAY TUBE VOLTAGE is defined in IEC 60788 (rm-36-03) as the highest permitted X-RAY TUBE VOLTAGE for specific operating conditions. In this standard, if specific operating conditions are not stated, it is to be assumed that the value referenced is unconditional and is thus the highest X-RAY TUBE VOLTAGE permitted for NORMAL USE of the item under consideration. Such a value cannot be higher, but is sometimes lower, than values permitted for certain separate sub-assemblies or parts of the item

2.102.2
PERCENTAGE RIPPLE in CONSTANT POTENTIAL HIGH-VOLTAGE GENERATORS
Unless otherwise stated, it is to be assumed that for a HIGH-VOLTAGE GENERATOR to be regarded as a CONSTANT POTENTIAL HIGH-VOLTAGE GENERATOR, the PERCENTAGE RIPPLE of its output voltage (under the relevant conditions) does not exceed 4

2.102.3
RADIATION QUANTITY for NOMINAL SHORTEST IRRADIATION TIME
The definition of NOMINAL SHORTEST IRRADIATION TIME refers to a required constancy of a RADIATION QUANTITY. In this standard the RADIATION QUANTITY concerned is AIR KERMA

2.102.4
IRRADIATION TIME
Generally the IRRADIATION TIME is measured in terms of LOADING TIME as the time interval between:

- the instant that the X-RAY TUBE VOLTAGE has risen for the first time to a value of 75 % of the peak value; and
- the instant at which it finally drops below the same value

3 General requirements

This clause of the General Standard applies except as follows:

Addition:

Mammographic X-RAY EQUIPMENT shall be designed so as not to deliver in NORMAL USE to any connected X-RAY TUBE ASSEMBLY a voltage greater than the NOMINAL X-RAY TUBE VOLTAGE for the X-RAY TUBE ASSEMBLY concerned.

5 Classification

This clause of the General Standard applies except as follows:

5.1 *Replacement:*

Mammographic X-RAY EQUIPMENT shall be CLASS I EQUIPMENT or INTERNALLY POWERED EQUIPMENT.

5.6 *Replacement:*

Unless otherwise specified, mammographic X-RAY EQUIPMENT or sub-assemblies thereof shall be classified as suitable for continuous connection to the SUPPLY MAINS in the STAND-BY STATE and for specified LOADINGS; see also 6.1 m) and 6.8.101.

6 Identification, marking and documents

This clause of the General Standard applies except as follows:

6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts

g) Connection to the supply

Addition:

- For mammographic X-RAY EQUIPMENT that is specified to be permanently installed, the information required in 6.1 g) of the General Standard may be stated in the ACCOMPANYING DOCUMENTS only.

h) Supply frequency

Addition:

- For mammographic X-RAY EQUIPMENT that is specified to be permanently installed, the information required in 6.1 h) of the General Standard may be stated in the ACCOMPANYING DOCUMENTS only.

j) Power input

Addition:

For mammographic X-RAY EQUIPMENT that is specified to be permanently installed, the following information may be stated in the ACCOMPANYING DOCUMENTS only.

The information on the power input shall be specified in terms of combinations of:

1) the rated MAINS VOLTAGE of the mammographic X-RAY EQUIPMENT in volts; see item g);
2) the number of phases; see item g);
3) the frequency in hertz; see item h);
4) the maximum permissible value for apparent resistance of supply mains in ohms;
5) the characteristics of OVER-CURRENT RELEASES required in the supply mains.

m) Mode of operation

Replacement:

The mode of operation – where appropriate, together with maximum permissible ratings – shall be stated in the ACCOMPANYING DOCUMENTS; see 6.8.101.

n) Fuses

Addition:

For mammographic X-RAY EQUIPMENT that is specified to be permanently installed, this subclause of the General Standard does not apply; see item j).

p) Output

Replacement:

This subclause of the General Standard does not apply.

Addition:

aa) Marking of compliance

If, for a mammographic X-RAY EQUIPMENT or sub-assembly thereof, compliance with this standard is to be marked on the outside of the EQUIPMENT, such marking shall be made in combination with the MODEL OR TYPE REFERENCE as follows:

+) IEC 60601-2-45

+) MODEL OR TYPE REFERENCE

6.7 Indicator lights and push-buttons

a) Colours of indicator lights

Addition after the first paragraph:

For a mammographic X-RAY EQUIPMENT, the colours to be used for indicator lights shall be as follows:

- the colour green shall be used at the CONTROL PANEL to indicate the state from which one further action leads to the LOADING STATE, if this state is indicated by a single function indicator light;

– for any indication of the LOADING STATE the colour yellow shall be used to indicate.

NOTE The colours of indicator lights need to be chosen according to the message to be given. Thus, the same operational state of an EQUIPMENT can have simultaneous indications in different colours depending upon the place of indication, for example green at the CONTROL PANEL and red at the entrance to the EXAMINATION ROOM.

6.8 ACCOMPANYING DOCUMENTS

6.8.1 General

Addition:

The ACCOMPANYING DOCUMENTS shall include a declaration of the dimensions of all available X-RAY FIELDS.

The ACCOMPANYING DOCUMENTS of any MAMMOGRAPHIC STEREOTACTIC DEVICE designed as an ACCESSORY for mammographic X-RAY EQUIPMENT shall contain:

- at least one MODEL OR TYPE REFERENCE to mammographic X-RAY EQUIPMENT with which it is designed to operate;
- a reference to the relevant standards with which the MAMMOGRAPHIC STEREOTACTIC DEVICE complies.

6.8.2 INSTRUCTIONS FOR USE

a) General information

Addition:

- INSTRUCTIONS FOR USE shall contain instructions for the inspection and safe use of all compression plates used with the mammographic X-RAY EQUIPMENT.
- INSTRUCTIONS FOR USE of mammographic stereotactic devices shall contain:
  - instructions for the safe handling and use of needles and CORE BIOPSY GUNS;
  - the designation of the types of needles and CORE BIOPSY GUNS with which they are designed to be used, including a warning against the use of any other types.

Electric output data shall be stated in the INSTRUCTIONS FOR USE in terms of LOADING FACTORS as described in 6.8.2 a) 1) to 6.8.2 a) 6).

The following combinations and data shall be stated:

1) the NOMINAL X-RAY TUBE VOLTAGE and the highest X-RAY TUBE CURRENT available at that voltage;
2) the highest X-RAY TUBE CURRENT and the highest X-RAY TUBE VOLTAGE available at that current;
3) the corresponding combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT which results in the highest electric output power;
4) the NOMINAL ELECTRIC POWER given as the highest constant electric output power in kilowatts which the X-RAY GENERATOR can deliver, for a LOADING TIME of 0,1 s at an X-RAY TUBE VOLTAGE of 30 kV or, if these values are not selectable, with an X-RAY TUBE VOLTAGE nearest to 30 kV and the value of LOADING TIME nearest to but not less than 0,1 s.

   The nominal electric power shall be given together with the combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT and the LOADING TIME;

   NOTE The values stated are only for characterising the equipment.

5) for mammographic X-RAY EQUIPMENT indicating precalculated or measured CURRENT TIME PRODUCT, the lowest CURRENT TIME PRODUCT or the combinations of LOADING FACTORS resulting in the lowest CURRENT TIME PRODUCT.

   If the value of the lowest CURRENT TIME PRODUCT depends upon the X-RAY TUBE VOLTAGE or upon certain combinations of values of LOADING FACTORS, the lowest CURRENT TIME PRODUCT may be given as a table or curve showing the dependence;

6) for mammographic X-RAY EQUIPMENT provided with automatic exposure control controlling the IRRADIATION TIME, the nominal shortest IRRADIATION TIME.

   If the NOMINAL SHORTEST IRRADIATION TIME depends upon LOADING FACTORS such as X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT, the ranges of these LOADING FACTORS for which the NOMINAL SHORTEST IRRADIATION TIME is valid shall be stated.

For mammographic X-RAY EQUIPMENT provided with AUTOMATIC EXPOSURE CONTROL controlling the X-RAY TUBE VOLTAGE or the X-RAY TUBE CURRENT, the range of the X-RAY TUBE VOLTAGE or the X-RAY TUBE CURRENT during the IRRADIATION shall be stated in the INSTRUCTIONS FOR USE.

Addition:

CONTROLLED AREA

The INSTRUCTIONS FOR USE shall draw the attention of the USER to the need to restrict access to the EQUIPMENT in accordance with local regulations for RADIOLOGICAL PROTECTION.

6.8.3 Technical description

Addition:

aa) cooling conditions

The accompanying documents shall state the cooling requirements for safe operation of the mammographic X-RAY EQUIPMENT, including:

- information concerning the heat dissipation into the surrounding air during NORMAL USE; and
- if applicable, information concerning the heat to be removed in NORMAL USE by any external cooling medium, and the details necessary for the provision concerned.

6.8.101 Reference to ACCOMPANYING DOCUMENTS

The following clauses and subclauses of this standard contain additional requirements concerning the content of ACCOMPANYING DOCUMENTS:

Mode of operation and specified LOADINGS	5.6 and 6.1 m)
Connection to the supply	6.1 g)
Number of phases of SUPPLY MAINS	6.1 g) and 6.1 j) 2)
Frequency of SUPPLY MAINS	6.1 h) and 6.1 j) 3)
Power input	6.1 j)
MAINS VOLTAGE	6.1 j) 1)
APPARENT RESISTANCE OF SUPPLY MAINS	6.1 j) 4) and 10.2.2
OVER-CURRENT RELEASE	6.1 j) 5)
Fuses	6.1 n)

Cooling conditions	6.8.3aa)
Electric output data, combinations of LOADING FACTORS	6.8.2 a) and 50.101
Suitable combinations for compliance test	50.1
Compliance with this standard	6.8.102
Central connection point PROTECTIVE EARTH CONDUCTOR	19.3
Range and interrelation of LOADING FACTORS	29.1.102 e)
Test conditions for AUTOMATIC EXPOSURE CONTROL	29.1.102 e)
Method to check the AUTOMATIC EXPOSURE CONTROL	29.1.104 d)
Combinations with the mammographic X-RAY EQUIPMENT	50.1
Suitable test combinations	50.1
LOADING FACTORS and modes of operation	50.101.1 a)
LOADING FACTORS in fixed combinations	50.101.2
Density correction of AUTOMATIC EXPOSURE CONTROL	50.102.2 dd) 2)

6.8.102 Statement of compliance

If for a mammographic X-RAY EQUIPMENT, or for a sub-assembly, compliance with this standard is to be stated, the statement shall be made in the following form:

mammographic X-RAY EQUIPMENT ... ++) IEC 60601-2-45:2001

++) MODEL OR TYPE REFERENCE

SECTION 2: ENVIRONMENTAL CONDITIONS

The clauses and subclauses of this section of the General Standard apply except as follows:

10 Environmental conditions

This clause of the General Standard applies except as follows:

10.2.2 Power supply

Item a)

Addition:

The internal impedance of a SUPPLY MAINS is to be considered sufficiently low for the operation of a mammographic X-RAY EQUIPMENT if the value of the APPARENT RESISTANCE OF SUPPLY MAINS does not exceed the value specified according to 6.1 j) 4).

NOTE The requirements of this standard are based upon the assumption that three-phase systems have a symmetrical configuration of the MAINS VOLTAGE with respect to earth and include a neutral conductor, and that single-phase systems are derived from such three-phase systems. A mammographic X-RAY EQUIPMENT is considered to comply with the requirements of this standard only if its specified NOMINAL ELECTRIC POWER can be demonstrated at an APPARENT RESISTANCE OF SUPPLY MAINS having a value not less than the APPARENT RESISTANCE OF SUPPLY MAINS specified according to 6.1 j) 4).

For this purpose, the APPARENT RESISTANCE OF SUPPLY MAINS R is determined according to the formula:

$$R = \frac{U_0 - U_1}{I_1}$$

where

U_0 is the no-load MAINS VOLTAGE;

U_1 is the MAINS VOLTAGE under load;

I_1 is the mains current under load.

The MAINS VOLTAGE shall be measured between

- phase and neutral in a single-phase system;
- phase and phase in a two-phase system;
- each two phases in a three-phase system.

The APPARENT RESISTANCE OF SUPPLY MAINS shall be measured by applying a single resistive load of a value corresponding approximately to the NOMINAL ELECTRIC POWER specified according to 6.8.2 a) 4), but not more than 5 kW.

SECTION 3: PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

The clauses and subclauses of this section of the General Standard apply except as follows:

15 Limitation of voltage and/or energy

This clause of the General Standard applies except as follows:

Addition:

aa) Detachable high-voltage cable connections to the X-RAY TUBE ASSEMBLY shall be designed so that the use of TOOLS is required to disconnect them or to remove their PROTECTIVE COVERS

Compliance is checked by inspection.

bb) Provision shall be made to prevent the appearance of an unacceptably high voltage in the MAINS PART or in any other low-voltage circuit.

NOTE This may be achieved for example:

- by provision of a winding layer or a conductive screen connected to the protective earth terminal between high-voltage and low-voltage circuits;
- by provision of a voltage-limiting device across terminals to which external devices are connected and between which an excessive voltage might arise if the external path becomes discontinuous.

Compliance is checked by inspection of design data and construction.

16 ENCLOSURES and PROTECTIVE COVERS

This clause of the General Standard applies except as follows:

Addition:

NOTE Requirements concerning the resistance and earthing of a flexible conductive screen of high-voltage cables connected to X-RAY TUBE ASSEMBLIES are given in IEC 60601-2-28.

19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

This clause of the General Standard applies except as follows:

19.3 Allowable values

Addition:

For mammographic X-RAY EQUIPMENT and sub-assemblies thereof the column on Type B and the rows on EARTH LEAKAGE CURRENT in NORMAL CONDITION and SINGLE FAULT CONDITION and on ENCLOSURE LEAKAGE CURRENT in NORMAL CONDITION of table IV, including the notes, of the General Standard apply.

The allowable values of EARTH LEAKAGE CURRENT are permitted for each sub-assembly of a mammographic X-RAY EQUIPMENT that is supplied by its own exclusive connection to the SUPPLY MAINS or to a central connection point, if the latter is fixed and permanently installed.

A fixed and permanently installed central connection point may be provided inside the outer ENCLOSURE or cover of the mammographic X-RAY EQUIPMENT. If other sub-assemblies such as an X-RAY SOURCE ASSEMBLY or ASSOCIATED EQUIPMENT are connected to the central connection point, the EARTH LEAKAGE CURRENT between such a central connection point and the external protective system may exceed the allowable values for any one of the single devices connected.

NOTE The limitation of the EARTH LEAKAGE CURRENTS within the environment of a mammographic X-RAY EQUIPMENT is intended to ensure that ACCESSIBLE PARTS do not become live and to prevent interference in other electrical equipment.

The provision of a central connection point is acceptable, as for fixed and PERMANENTLY INSTALLED EQUIPMENT the interruption of the PROTECTIVE EARTH CONDUCTOR is not considered to be a SINGLE FAULT CONDITION. However, in such cases, adequate information on the combination of sub-assemblies needs to be provided.

19.3, table IV, note 3)

Addition:

For permanently installed mammographic X-RAY EQUIPMENT, the EARTH LEAKAGE CURRENT under NORMAL CONDITION and SINGLE FAULT CONDITION shall not exceed 10 mA (see 19.3 a)).

For permanently installed mammographic X-RAY EQUIPMENT, regardless of waveform and frequency, the EARTH LEAKAGE CURRENT under NORMAL CONDITION and SINGLE FAULT CONDITION shall not exceed 20 mA (see 19.3b)).

19.3, table IV, note 4)

Addition:

For mobile equipment and transportable equipment, the earth leakage current under normal condition shall not exceed 2,5 mA and under single-fault condition shall not exceed 5 mA. The enclosure leakage current under single-fault condition shall not exceed 2 mA.

20 Dielectric strength

This clause of the General Standard applies except as follows:

20.3 Values of test voltages

Addition:

The dielectric strength of the electrical insulation of high-voltage circuits shall be sufficient to withstand the test voltages for the durations given in 20.4 a).

The test voltage shall be 1,2 times the NOMINAL X-RAY TUBE VOLTAGE.

The test shall be carried out with the X-RAY TUBE ASSEMBLY and its interconnecting cables disconnected, unless the X-RAY TUBE ASSEMBLY is integrated with other parts of the high-voltage circuit or the MANUFACTURER specifies that the X-RAY TUBE ASSEMBLY is to be connected during the test.

If the HIGH-VOLTAGE GENERATOR can be tested only with the X-RAY TUBE connected and if the X-RAY TUBE does not allow the HIGH-VOLTAGE GENERATOR to be tested with a test voltage of 1,2 times the NOMINAL X-RAY TUBE VOLTAGE, the test voltage shall be lower but not less than 1,1 times that voltage.

20.4 Tests

Item *a)*

Addition:

The high-voltage circuits are tested by applying a test voltage of 50 % of its final value according to 20.3 and raising it over a period of 10 s or less to the final value which then is maintained for the duration of 3 min.

Item *d)*

Replacement:

During the dielectric strength test, the test voltage in the high-voltage circuit shall be maintained in the range of 100 % to 105 % of the value required.

Item *f)*

Addition:

During the dielectric strength test, slight corona discharges in the high-voltage circuit are to be disregarded if they cease when the test voltage is lowered to 110 % of the voltage to which the test condition is referred.

Item *l)*

Addition:

The test voltage for the dielectric strength testing of the stator and stator circuit used for the operation of the rotating ANODE of the X-RAY TUBE is to be referred to the voltage existing after reduction of the stator supply voltage to its steady-state operating value.

Additional item aa):

1) *If the test is to be performed without disconnecting the X-RAY TUBE ASSEMBLY, LOADING is to be applied in accordance with the MANUFACTURER'S recommendations, if any, with particular care to avoid exceeding permitted values of X-RAY TUBE LOAD when the applied X-RAY TUBE VOLTAGE exceeds the NOMINAL X-RAY TUBE VOLTAGE.*
2) *If the dielectric strength test is performed with an X-RAY TUBE connected and the high-voltage circuit is not accessible for the measurement of the test voltage applied, appropriate measures are to be taken to ensure that the values lie within the limits required in 20.4 d).*

SECTION 4: PROTECTION AGAINST MECHANICAL HAZARDS

The clauses and subclauses of this section of the General Standard apply except as follows:

21 Mechanical strength

This clause of the General Standard applies except as follows:

Addition:

21.101 Application of maximum compression force

21.101.1 Motion of ANTI-SCATTER GRID

For mammographic X-RAY EQUIPMENT with a moving ANTI-SCATTER GRID, the application of the maximum force attainable for the COMPRESSION DEVICE shall not impede the motion of the ANTI-SCATTER GRID.

Compliance is determined by the following test:

a) Test equipment

The following test equipment is required:

- *appropriately sized objects, one for each image receptor format, leading to sufficiently realistic force distributions when under compression. The objects shall be sand-filled bags or soft rubber blocks. Their thickness shall be in the range from 20 mm to 50 mm. The objects shall be 100 mm to 120 mm long and wide for the smallest image receptor format and 120 mm to 150 mm long and wide for larger formats;*
- *an aluminium plate of 2 mm thickness and of dimensions sufficient to intercept the whole X-RAY BEAM when mounted as described below;*

- *if the X-RAY EQUIPMENT uses RADIOGRAPHIC FILMS:*
  - *a densitometer, covering the optical density range from 0 to 3,5;*
  - *radiographic cassettes with intensifying screens and radiographic films for each image format.*

b) Test procedure

Position the X-RAY TUBE – image receptor assembly to acquire a cranio-caudal projection of the breast and set the X-RAY EQUIPMENT in a condition that is provided for grid mammography. Mount a compression plate that is designed for the maximum attainable compression force and for the image receptor format used. Fix the aluminium plate between the X-RAY SOURCE ASSEMBLY and the compression plate so that it will completely cover the X-RAY BEAM. Place the object on the PATIENT SUPPORT, centred laterally, and with one edge as close as possible to that edge of the PATIENT SUPPORT that is provided to be adjacent to the PATIENT's chest wall. If the object is a sand-filled bag, shape it by hand to maximize the surface areas that will be in contact with the PATIENT SUPPORT and the compression plate. Actuate the breast COMPRESSION DEVICE to the maximum attainable compression force. For X-RAY EQUIPMENT using RADIOGRAPHIC FILMS, select an X-RAY TUBE VOLTAGE of 25 kV to 30 kV and a CURRENT TIME PRODUCT that will lead to an optical density of 1,0 to 2,0 in the darkest part of the RADIOGRAPHIC FILM, which will be outside the image of the object under compression. Irradiate and process the RADIOGRAPHIC FILM. For X-RAY EQUIPMENT using a non-film image receptor, select an X-RAY TUBE VOLTAGE and CURRENT TIME PRODUCT appropriate for the image receptor; irradiate the image receptor and display the image.

Evaluate the RADIOGRAM. In case of impeded grid motion owing to the high compression force, grid lines or some other image of the ANTI-SCATTER GRID structure shall be visible in the area outside the image of the object under compression.

If the ANTI-SCATTER GRID structure is visible, repeat the test but without applying a compression force, in order to verify whether the compression force is the cause.

Repeat the test procedure for all image receptor formats.

c) Interpretation of test results

Compliance is achieved if the application of the compression force does not increase the visibility of the ANTI-SCATTER GRID structure.

21.101.2 Strength of compression plates

Compression plates and their mountings, unless marked to indicate the maximum compression force permitted to be applied, shall withstand the maximum compression force attainable when they are fitted to the EQUIPMENT. The marking may take the form of coding related to an explanation in the INSTRUCTIONS FOR USE.

Compliance is determined by the following test:

a) Test equipment

Test objects as described in 21.101.1 are required.

b) Test procedure

Position the X-RAY TUBE – image receptor assembly to acquire a cranio-caudal projection of the breast. Mount a compression plate that is designed for the maximum attainable compression force. Take the test object designed for the same image receptor format as the compression plate and place it on the PATIENT SUPPORT, centred laterally, and with one edge as close as possible to that edge of the PATIENT SUPPORT that is provided to be adjacent to the PATIENT's chest wall. If the object is a sand-filled bag, shape it by hand to maximize the surface areas that will be in contact with the PATIENT SUPPORT and the compression plate.

Actuate the breast COMPRESSION DEVICE to the maximum attainable compression force. Then relax the force.

c) Interpretation of test results

Inspect the compression plate and associated parts for any signs of damage, especially for fissures. For compliance, the compression plates and associated parts are to be free from breakage, visible damage and permanent distortion.

22 Moving parts

This clause of the General Standard applies except as follows:

Addition:

22.101 Motion of X-RAY TUBE – image receptor assembly

The assembly shall be capable of being rigidly fixed in any position where it is designed to operate. Once fixed in any such position, the assembly shall not move without OPERATOR intervention. Movement of the assembly shall require continuous actuation by the OPERATOR. In the event of interruption of the SUPPLY MAINS, the assembly shall not put any resultant force exceeding 20 N on any part of the PATIENT.

When the breast COMPRESSION DEVICE is actuated to a force of more than 50 N, the speed or step size of any power-driven movements of the assembly as a whole shall be limited so that the OPERATOR will have adequate control for fine correction of its position without endangering the PATIENT. Motions needed for stereotactic imaging are excluded from this requirement.

22.102 COMPRESSION DEVICE

22.102.1 General

All mammographic X-RAY EQUIPMENT shall be fitted with a breast COMPRESSION DEVICE.

22.102.2 Control of compression movements

All switches controlling movement for the application of compression shall be of the type requiring continuous actuation while movement takes place. The X-RAY EQUIPMENT shall provide means for hands-free initiation of compression. It shall include means for fine adjustment of motion during the application of the compression force and for decompression. All functions shall be accessible from both sides of the position of the PATIENT.

Means shall be provided for the OPERATOR to prevent automatic decompression.

In the event of interruption of SUPPLY MAINS, the compression shall be maintained. However, means shall be provided for manually achieving complete decompression.

22.102.3 Range of movement

In all conditions of NORMAL USE, the available range of movement of the COMPRESSION DEVICE shall allow all those parts of the compression plate that are designed to be in contact with the breast to be brought within 10 mm of the surface of the PATIENT SUPPORT.

NOTE This requirement is intended to ensure that adequate compression of small or thin breasts is not prevented by limitation of the available movement of the compression plate. The extent of compression applied to any particular PATIENT is controlled by the OPERATOR and may be limited by restriction of the available operating force; see 22.102.5.

22.102.4 Design of compression plates

Compression plates intended for special purpose are not subject to this requirement.

Compression plates shall be transparent so that the skin of the PATIENT remains visible when in contact with them. Unless other means for indication are provided, the mammographic X-RAY EQUIPMENT shall include at least one compression plate for each image receptor format used in an AUTOMATIC EXPOSURE CONTROL mode marked to indicate the range of sensor positions available in NORMAL USE.

The chest wall edge of the compression plate must be straight and parallel to the chest wall edge of the image receptor unless designed otherwise. It may be bent upward to allow for patient comfort. However the front edges shall not appear on the image.

22.102.5 Compression force

COMPRESSION DEVICES shall satisfy the following requirements in respect of the application and indication of the compression force in all orientations specified for NORMAL USE:

- no COMPRESSION DEVICE shall be able to apply a force exceeding 300 N;
- for power-driven compression, the COMPRESSION DEVICE shall be able to apply a force of at least 150 N, and it shall be unable to apply a force exceeding 200 N;
- for power-driven compression, the available operating force shall be adjustable down to 70 N or less;
- if the value of the applied force is displayed, the indication shall be accurate to ±20 N.

NOTE The interests of safety make it undesirable generally to permit any unit other than the newton. Countries wishing to use obsolete non-SI units can do so by national variation, tolerating the display of kilograms or pounds.

Compliance is checked by measurement.

a) Test equipment

The following test equipment is required:

- *a force balance;*
- *a soft rubber block, 20 mm to 50 mm thick, and 100 mm to 120 mm long and wide.*

b) Test procedure

Position the X-RAY TUBE – image receptor assembly to acquire a cranio-caudal projection of the breast. Place the force balance on the PATIENT SUPPORT and fix it so that it will not fall down in any orientation. Place the soft rubber block on the sensitive area of the force balance. Operate the COMPRESSION DEVICE, thus clamping the soft rubber block, and record the reading of the balance. Measure the highest achievable forces for all compression modes. If the force is displayed at the X-RAY EQUIPMENT then perform at least five additional measurements for lower compression forces, equally distributed over the range from zero compression to the maximum attainable compression force, and record all displayed values in combination with the readings of the balance. Repeat the test procedure for at least three other orientations of the X-RAY TUBE – image receptor assembly in order to cover the whole range of angles possible with the X-RAY EQUIPMENT sufficiently.

Repeat this test procedure for all modes of power-driven compression after adjusting the available operating force down to its minimum.

c) Interpretation of measured data

Determine compliance by comparing MEASURED VALUES with required values and, if the compression force is displayed, with the above requirements of accuracy.

22.103 MAMMOGRAPHIC STEREOTACTIC DEVICE

22.103.1 Positioning of X-RAY SOURCE ASSEMBLY for stereotactic imaging

In stereotactic imaging, defined angular positions shall be provided for the X-RAY SOURCE ASSEMBLY. The X-RAY SOURCE ASSEMBLY shall be capable of being rigidly fixed in any of these positions. Once fixed in any such position, the X-RAY SOURCE ASSEMBLY shall require OPERATOR intervention to release.

22.103.2 Motion of APPLIED PARTS during imaging and biopsy or marker placing

Under constant compression force, there shall be no displacement between the PATIENT SUPPORT and the compression plate of more than ±0,5 mm and ±0,5° relative to each other, and their displacement relative to the PATIENT shall not exceed ±2 mm and ±2°. The movement of the needle holder or CORE BIOPSY GUN holder with a needle inserted in it shall require continuous actuation and control by the OPERATOR.

22.103.3 Biopsy needle positioning accuracy of MAMMOGRAPHIC STEREOTACTIC DEVICES

The accuracy of the biopsy needle tip position in x, y, and z directions shall be within ±1 mm in the specified stereotactic biopsy volume.

Compliance is checked by measurement.

a) Test equipment

A stereotactic TEST DEVICE of a design which allows testing for different biopsy needle directions is required for the test. It consists of a mounting plate which is perforated so that it can serve as a locator for the test needles. At least three steel needles of different lengths are to be fixed in the mounting plate, the outer parts perpendicular to its surface and pointing in the same direction. An example of the arrangement is shown in figure 101.

The steel needles are test needles, their tips serve as test objects. They shall be placed in a pattern so that the specified stereotactic biopsy volume can be covered. It shall be possible to locate one of them within ±5 mm of the centre of that volume, and two of the other test needle tips also inside the specified stereotactic biopsy volume and within 10 mm of the extreme x, y, z points that are intended to be reconstructed with the MAMMOGRAPHIC STEREOTACTIC DEVICE.

b) Test procedure

Measure the biopsy needle length and compare the result to the nominal biopsy needle length, or to the biopsy needle length value stored or programmed in the MAMMOGRAPHIC STEREOTACTIC DEVICE. The measured length shall agree with the nominal length to within ±0,3 mm. Place the TEST DEVICE on the PATIENT SUPPORT of the MAMMOGRAPHIC STEREOTACTIC DEVICE, so that one of the test needle tips is located to within ±5 mm of the centre of the specified stereotactic biopsy volume, and two of the other test needle tips are also located inside the specified stereotactic biopsy volume and within 10 mm of the extreme x, y, z points that are intended to be reconstructed. An attenuating, homogeneous material, for example 2 mm Al, may be attached close to the X-RAY SOURCE ASSEMBLY.

Select a FOCAL SPOT with which the MAMMOGRAPHIC STEREOTACTIC DEVICE is specified to be used.

Position the X-RAY TUBE – image receptor assembly to acquire a cranio-caudal projection of the breast. Acquire a pair of stereo views. On each image select all projections of the test needle tips within the specified stereotactic biopsy volume and reconstruct their x, y, z positions. For each test needle, position the biopsy needle tip according to the position calculated by the MAMMOGRAPHIC STEREOTACTIC DEVICE. Measure and record the differences in x, y, z positions between each test needle tip and the biopsy needle tip. Repeat the procedure with the X-RAY TUBE ASSEMBLY – image receptor assembly rotated to the extremities of the range specified by the MANUFACTURER for clinical use of angular deviation in each direction and also to any intermediate deviations of 90 degrees or multiples thereof. If the MAMMOGRAPHIC STEREOTACTIC DEVICE is designed for more than one biopsy needle direction relative to the X-RAY TUBE ASSEMBLY – image receptor assembly, then repeat the procedure at six different directions within the range specified by the MANUFACTURER for clinical use, including at least two directions at extremities of the specified range.

c) Interpretation of measured data

Compare the differences in x, y, and z directions to the requirement above.

NOTE As visibility of all needle tips on the RADIOGRAMS is essential for the test procedure, it is important to avoid any overexposure of RADIOGRAPHIC FILM. Depending on the type of X-RAY EQUIPMENT, the attenuating material addressed in the description of the test procedure might be helpful for reaching this aim.

24 Stability in NORMAL USE

This clause of the General Standard applies except as follows:

Addition:

24.101 Mammographic X-RAY EQUIPMENT shall not overbalance if subjected to a force of 25 % of its weight or 220 N, whichever is less.

The force is to be applied in the direction and location most likely to overbalance the mammographic X-RAY EQUIPMENT. Legs or wheels shall be blocked in the most unfavourable position. The force shall be applied at the highest point or at a point 150 cm above floor level, whichever is the lower.

Mammographic X-RAY EQUIPMENT shall fulfil these requirements in all working conditions of NORMAL USE.

SECTION 5: PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

The clauses and subclauses of this section of the General Standard apply except as follows:

General

Addition:

NOTE There are two clauses in section 4 (clause 21, clause 22) which contain requirements of mechanics, but which, in actual fact, also address protection against hazards from unwanted or excessive RADIATION.

29 X-RADIATION

This clause of the General Standard applies except as follows:

29.1 *Replacement:*

29.1 X-RADIATION generated by mammographic X-RAY EQUIPMENT

Addition:

29.1.101 General requirements

Mammographic X-RAY EQUIPMENT shall comply with the applicable requirements of IEC 60601-1-3.

29.1.102 Indication of operational states

NOTE For indicator lights on the CONTROL PANEL, the colours required in 6.7a) apply.

a) READY STATE

Visible indication shall be provided on the control panel indicating the state when one further actuation of a control will initiate the LOADING of the X-RAY TUBE.

Means shall be provided for a connection to enable this state also to be indicated remotely from the CONTROL PANEL.

NOTE The actuation of a single control with two consecutive positions – as used for starting a rotating ANODE and setting other preparatory conditions – is regarded as a single actuation.

b) LOADING STATE

The LOADING STATE shall be indicated by an indicator light on the CONTROL PANEL. Additionally,

- provision shall be made for a signalling device, audible at the location from which the EQUIPMENT is operated, to indicate the instant of termination of LOADING,

c) Indication of the X-RAY SOURCE ASSEMBLY selected

Where a mammographic X-RAY EQUIPMENT has provisions to select more than one X-RAY TUBE an indication of the X-RAY TUBE selected shall be provided on the CONTROL PANEL prior to the LOADING of the X-RAY TUBE.

Where a mammographic X-RAY EQUIPMENT has provisions to initiate the LOADING of more than one X-RAY TUBE from a single location, means shall be provided for the connection of an additional indication to be given at or near each X-RAY TUBE selectable.

d) Indication of automatic modes

For mammographic X-RAY EQUIPMENT operating with AUTOMATIC EXPOSURE CONTROL the preselected mode of automatic operation shall be indicated on the CONTROL PANEL.

e) Ranges in AUTOMATIC EXPOSURE CONTROL

For mammographic X-RAY EQUIPMENT in which automatic control of exposure is achieved by varying one or more LOADING FACTORS, information about the range and interrelation of these LOADING FACTORS shall be given in the INSTRUCTIONS FOR USE.

Compliance is checked by inspection and by the appropriate functional tests.

29.1.103 Limitation of RADIATION output

a) Means shall be provided to limit the electric energy to be delivered by the use of fixed or preselected combinations of suitable LOADING FACTORS and modes of operation.

b) Each LOADING shall be initiated and maintained by means of a control requiring continuous actuation by the OPERATOR.

c) It shall not be possible to initiate any unintended subsequent IRRADIATION without releasing the control by which the previous IRRADIATION was initiated.

d) Means shall be provided for the OPERATOR to terminate each IRRADIATION at any time before its intended completion.

e) Any control by which the LOADING of an X-RAY TUBE can be initiated shall be safeguarded against unintended actuation.

Compliance is checked by inspection and by the appropriate functional tests.

29.1.104 Safety measures against excessive RADIATION output

a) In the case of a failure of its normal termination the IRRADIATION shall be terminated by a safety measure.

b) If the normal termination is not effected upon the basis of a RADIATION measurement, continuous actuation by the OPERATOR in accordance with 29.1.103 b) shall suffice as the safety measure required in item a) above.

c) If the normal termination depends upon a RADIATION measurement, the safety measure shall comprise means for termination of IRRADIATION in the event of a failure of the normal termination.

   The CURRENT TIME PRODUCT shall be limited to no more than 1 200 mAs per IRRADIATION.

   The system for normal termination of IRRADIATION and the system used for the safety measure shall be separated so that a failure in one system does not affect termination by the other system.

A visible indication at the CONTROL PANEL shall be provided whenever a LOADING has been terminated by the safety means required. Another LOADING in the same mode of operation shall not be possible until a control device provided for resetting has been operated at the CONTROL PANEL.

d) For mammographic X-RAY EQUIPMENT provided with AUTOMATIC EXPOSURE CONTROL a method by which the OPERATOR can verify the functioning of the AUTOMATIC EXPOSURE CONTROL shall be provided and the INSTRUCTIONS FOR USE shall contain the description of that method.

Compliance is checked by inspection and by the appropriate functional tests.

29.1.105 RADIATION output

At any DIRECT FOCAL DISTANCE, where the mammographic X-RAY EQUIPMENT is designed to operate, it shall be capable of producing a minimum AIR KERMA rate of 7,0 mGys^{-1} for an IRRADIATION TIME of at least 3 s, measured 4,5 cm above the PATIENT SUPPORT and 5,0 cm from the chest wall side on the centre line, at 28 kV and using molybdenum as material for the TARGET and for the FILTRATION. This applies to the large FOCAL SPOT.

Arrange the X-RAY SOURCE ASSEMBLY, the DIAPHRAGM and the RADIATION DETECTOR for measurement under NARROW BEAM CONDITION without the compression plate. Ensure that the RADIATION QUALITY of the X-RAY BEAM emerging from the X-RAY SOURCE ASSEMBLY complies with applicable specified conditions for NORMAL USE. If no such conditions are specified, ensure that the TOTAL FILTRATION in the X-RAY SOURCE ASSEMBLY is such as to comply with the General Standard as applicable.

Compliance is checked by tests.

Additional subclauses:

The additional subclauses of clause 29 of the collateral standard IEC 60601-1-3 apply, except as follows

29.201.5 TOTAL FILTRATION in X-RAY EQUIPMENT

Replacement of the first paragraph:

In mammographic X-RAY EQUIPMENT, the TOTAL FILTRATION arising from material in the X-RAY BEAM incident to the PATIENT, excluding the material of any compression plate, shall be:

29.201.9 Test for HALF-VALUE LAYER

Addition:

For X-RAY EQUIPMENT specified exclusively for mammography, ensure that the compression plate is not in the X-RAY BEAM during the determination.

NOTE The exclusion of the compression plate from the measurement is not in contradiction to 29.201.2 of IEC 60601-1-3 because mammographic X-RAY EQUIPMENT usually includes perforated compression plates for breast biopsy.

29.203.4 Correspondence between X-RAY FIELD and IMAGE RECEPTION AREA

Replacement:

Means shall be provided to enable the X-RAY FIELD to be positioned to cover the region of interest and the SENSITIVE VOLUMES of the AUTOMATIC EXPOSURE CONTROL.

When the X-RAY FIELD is adjusted in NORMAL USE for full coverage of the IMAGE RECEPTION AREA, it shall correspond to the PATIENT SUPPORT and the IMAGE RECEPTION AREA within the following limits.

The X-RAY FIELD

a) shall extend to the edge of the PATIENT SUPPORT that is designed to be adjacent to the chest wall of the PATIENT and shall not extend beyond this edge by more than 5 mm;

b) shall not extend by more than 2 % of the DIRECT FOCAL DISTANCE beyond all edges of the IMAGE RECEPTION AREA.

NOTE The position of the tolerance zone in item b) above has been changed so as not to exclude the possibility of irradiating the entire film area of mammograms. This permits the USER to avoid transparent margins on the film, where this is considered to be justified in the interests of reading diagnostic information from the mammograms, especially in circumstances where the masking of films during viewing is impracticable.

See annex BB for rationale.

29.207 PRIMARY PROTECTIVE SHIELDING

Replacement:

29.207.1 Requirements

Mammographic X-RAY EQUIPMENT shall be provided with PRIMARY PROTECTIVE SHIELDING in accordance with the requirements below. These requirements shall be met for all combinations of X-RAY FIELDS and perpendicular distances from the IMAGE RECEPTOR PLANE to the position of the FOCAL SPOT in NORMAL USE.

The PRIMARY PROTECTIVE SHIELDING shall extend at least to the projection of the PATIENT SUPPORT at the edge designed to be adjacent to the PATIENT's chest wall and at the other edges shall extend beyond the X-RAY FIELD by at least 1 % of the perpendicular distance from the IMAGE RECEPTOR PLANE to the position of the FOCAL SPOT.

The maximum permitted AIR KERMA is 1 µGy per IRRADIATION.

The reference X-RAY TUBE VOLTAGE for compliance shall be the NOMINAL X-RAY TUBE VOLTAGE.

The reference LOADING FACTORS for compliance shall be those corresponding to the MAXIMUM ENERGY input in a single LOADING according to the RADIOGRAPHIC RATINGS.

If LOADING FACTORS can be controlled only by an AUTOMATIC CONTROL SYSTEM, the ACCOMPANYING DOCUMENTS shall include instructions for obtaining appropriate LOADING FACTORS for test.

Compliance is checked by inspection, by examination of the design documentation and ACCOMPANYING DOCUMENTS, and by the test described in 29.207.2 of IEC 60601-1-3.

29.208 Protection against STRAY RADIATION

Addition:

29.208.101 PROTECTIVE BARRIER

Mammographic X-RAY EQUIPMENT for which a SIGNIFICANT ZONE OF OCCUPANCY is designated shall have a PROTECTIVE BARRIER which is designed to be placed between the SIGNIFICANT ZONE OF OCCUPANCY and the region of the PATIENT SUPPORT. The PROTECTIVE BARRIER shall not prevent the OPERATOR from observing the PATIENT during the acquisition of mammograms. It shall extend from not more than 15 cm above the floor to a height of not less than 185 cm, and its width shall not be smaller than 60 cm.

NOTE The height of a SIGNIFICANT ZONE OF OCCUPANCY as specified in IEC 60601-1-3 does not necessarily imply that the PROTECTIVE BARRIER as specified in this standard has the same height.

With an emitting TARGET of molybdenum, an X-RAY TUBE VOLTAGE of 35 kV with a PERCENTAGE RIPPLE of not more than 4 and a TOTAL FILTRATION of 0,03 mm molybdenum, the ATTENUATION EQUIVALENT of this PROTECTIVE BARRIER shall not be smaller than 0,08 mm of lead.

The PROTECTIVE BARRIER shall be permanently marked with its ATTENUATION EQUIVALENT with reference to this standard.

NOTE The particular requirements in this subclause are added for practical reasons, mainly in order to provide a lower limit for the ATTENUATION EQUIVALENT of PROTECTIVE BARRIERS that is usually appropriate for mammographic X-RAY EQUIPMENT. However, their fulfilment does not necessarily imply fulfilment of the requirements of the General Standard and of local regulations and requirements for the limits of effective dose applicable to the OPERATOR.

36 Electromagnetic compatibility

This clause of the General Standard applies except as follows:

Replacement:

IEC 60601-1-2 shall be applicable.

SECTION 6: PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

The clauses and subclauses of this section of the General Standard apply.

SECTION 7: PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

The clauses and subclauses of this section of the General Standard apply except as follows:

42 Excessive temperatures

This clause of the General Standard applies except as follows:

42.1 *Addition:*

Restrictions on allowable maximum temperature for parts in contact with oil shall not apply to parts wholly immersed in oil.

SECTION 8: ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

The clauses and subclauses of this section of the General Standard apply except as follows:

Addition:

NOTE Many variable factors affect the relationship between the output parameters of a mammographic X-RAY EQUIPMENT and the attainment of particular mammographic results in the X-RAY EQUIPMENT. Even when there is compliance with this standard, it is not to be expected in daily radiographic practice that LOADING FACTORS determined for any purpose on one installation can be transferred to other installations for the same purpose, without correction.

50 Accuracy of operating data

This clause of the General Standard applies except as follows:

Replacement:

50.1 General

For mammographic X-RAY EQUIPMENT or sub-assemblies thereof it shall be possible to demonstrate compliance with the requirements of 50.102 and 50.103 by application of the relevant tests under the conditions of 50.104 and 50.105 in all combinations of sub-assemblies that are specified in the ACCOMPANYING DOCUMENTS as being compatible for compliance with this standard.

Compliance of mammographic X-RAY EQUIPMENT or sub-assemblies thereof with the requirements of 50.102 and 50.103 is to be tested in one or more suitable combinations with X-RAY TUBES and appropriate sub-assemblies, specified in the ACCOMPANYING DOCUMENTS as suitable for this purpose.

50.101 Indication of electric and RADIATION output

50.101.1 General

a) Adequate information shall be available to the OPERATOR, before, during and after the LOADING of an X-RAY TUBE, about fixed, permanently or semi-permanently preselected or otherwise determined LOADING FACTORS or modes of operation so as to enable the OPERATOR to select appropriate conditions for the IRRADIATION and subsequently to obtain data necessary for the estimation of the ABSORBED DOSE received by the PATIENT.

b) Discrete values of indicated LOADING FACTORS having an essentially proportional relation to the amount of X-RADIATION produced, particularly values for X-RAY TUBE CURRENT, LOADING TIME and CURRENT TIME PRODUCT, shall be chosen from the series R'10 or R'20 according to ISO 497.

   If compliance with this standard of LOADING FACTORS indicated in a series R'10 is to be determined by using the theoretical (calculated) values according to annex CC, this shall be indicated in the ACCOMPANYING DOCUMENTS.

c) The units of indication shall be as follows:
   - X-RAY TUBE VOLTAGE in kilovolts (kV);
   - CURRENT TIME PRODUCT in milliampere seconds (mAs)
   - X-RAY TUBE CURRENT in milliamperes (mA);
   - LOADING TIME in seconds (s).

Compliance with the requirements of 50.101.1 a) to 50.101.1 c) is checked by inspection.

50.101.2 Shortened indication

For mammographic X-RAY EQUIPMENT operating with one or more fixed combinations of LOADING FACTORS the indication on the CONTROL PANEL may be confined to the value of only one of the significant LOADING FACTORS for each combination, for example the value of X-RAY TUBE VOLTAGE.

In this case the indication of the corresponding values of the other LOADING FACTORS in each combination shall be given in the INSTRUCTIONS FOR USE.

In addition these values shall be listed in a form suitable to be displayed at a prominent location on or near the CONTROL PANEL.

50.102 Reproducibility, linearity and constancy

NOTE 50.101 and 50.102 contain requirements on operating data for mammographic X-RAY EQUIPMENT that are considered essential for protection against incorrect output.

50.102.1 Reproducibility of the RADIATION output without AUTOMATIC EXPOSURE CONTROL activated

The coefficient of variation of MEASURED VALUES of AIR KERMA shall be not greater than 0,05 for any combination of LOADING FACTORS.

Compliance is determined by tests according to 50.104, 50.105 and table 101 in suitable test combinations; see 50.1.

50.102.2 Linearity and constancy

a) Linearity of AIR KERMA over limited intervals of LOADING FACTORS

   The quotients of the average of the MEASURED VALUES of AIR KERMA divided by the pre-selected values or the INDICATED VALUES of CURRENT TIME PRODUCT, or the product of the values of X-RAY TUBE CURRENT and IRRADIATION TIME, obtained at any two settings of the above LOADING FACTORS when pre-selection is continuous and the pre-selected values differ by a factor as close as possible to but not exceeding 2, shall not differ by more than 0,2 times the mean value of these quotients:

$$\left| \frac{\overline{K}_1}{Q_1} - \frac{\overline{K}_2}{Q_2} \right| \leq 0{,}2 \frac{\frac{\overline{K}_1}{Q_1} + \frac{\overline{K}_2}{Q_2}}{2}$$

$$\left| \frac{\overline{K}_1}{I_1 t_1} - \frac{\overline{K}_2}{I_2 t_2} \right| \leq 0{,}2 \frac{\frac{\overline{K}_1}{I_1 t_1} + \frac{\overline{K}_2}{I_2 t_2}}{2}$$

where

$\overline{K}_1, \overline{K}_2$ are the averages of the MEASURED VALUES of AIR KERMA;

Q_1 , Q_2 are the indicated CURRENT TIME PRODUCTS;

I_1 , I_2 are the indicated X-RAY TUBE CURRENTS;

t_1 , t_2 are the indicated IRRADIATION TIMES.

Compliance is determined by tests according to 50.104, 50.105 and table 101 in suitable test combinations; see 50.1.

b) Constancy of the AUTOMATIC EXPOSURE CONTROL (AEC) on film-screen receptors

The AEC shall be capable of maintaining film optical density within ±0,15 of average optical density when thickness of a homogeneous material is varied over a range of 2 cm to 6 cm and the X-RAY TUBE VOLTAGE is varied appropriately for such thickness over the range recommended by the MANUFACTURER for clinical use. The appropriate combination of X-RAY TUBE VOLTAGE and thickness of the object is to be stated by the MANUFACTURER. The AEC shall be operable in all combinations of EQUIPMENT configurations, e.g. ANTI-SCATTER GRID, no ANTI-SCATTER GRID, magnification and (if applicable) stereotactic modes, and with various TARGET/FILTER combinations. If this requirement cannot be met, a technique chart shall be developed showing appropriate techniques (kV, ANODE/FILTER and density control settings) for different breast thickness and compositions that shall be such that optical density within ±0,15 of the average under AEC conditions can be produced.

The value of ±0,15 shall be applicable for the region of the maximum gradients for the characteristic curve of the X-RAY IMAGE RECEPTOR.

aa) *Test method*

Measure the optical density of RADIOGRAMS of PHANTOMS made of breast TISSUE EQUIVALENT MATERIAL, water or polymethyl methacrylate (PMMA), produced with the AUTOMATIC EXPOSURE CONTROL in operation. Determine the variations of density for different PHANTOM thickness and for different X-RAY TUBE VOLTAGES.

bb) Test arrangement

Use a test arrangement with following characteristics:

1) *A DIRECT FOCAL DISTANCE, remaining unchanged for all tests in a series;*

2) *An 18 x 24 RADIOGRAPHIC CASSETTE for mammography, the same cassette being used for all tests in a series. If the mammographic X-RAY EQUIPMENT includes more than one PATIENT SUPPORT then the AEC shall also be tested using these arrangements.*

3) *To test the thickness range of 2 cm to 6 cm in steps of 1 cm. The size of the PHANTOMS shall provide sufficient coverage of the AEC detector, for example 10 cm x 15 cm or a semicircle with a radius of 10 cm. A larger size is recommended to generate a clinical SCATTERED RADIATION.*

4) *If the grid can be removed, or PATIENT SUPPORT without a grid is provided, the AEC function shall also be tested for these configurations.*

5) *Provision for accurate and reproducible film processing and for measuring the optical density of processed RADIOGRAPHIC FILMS. The film processor stability during the AEC test shall regularly be tested with a sensitometer test, at least in the beginning, half way through the test and at the end. It is also very important that this test is done in succession, it is not appropriate to divide the test into different parts, and it is also impossible to make this test if the processor is not stable. If the processor has a small drift during the test period, this drift must be taken into consideration when making the evaluation. The densitometer shall be designed for mammography and calibrated for proper film-base.*

cc) RADIOGRAPHIC FILM and INTENSIFYING SCREEN

Use same combination of RADIOGRAPHIC FILM, INTENSIFYING SCREEN and RADIOGRAPHIC CASSETTE according to the information given in the INSTRUCTIONS FOR USE, if a different INTENSIFYING SCREEN is recommended for special procedures, i.e. stereotaxy or magnification, the AEC shall also be tested using this arrangement.

dd) *Setting the AUTOMATIC EXPOSURE CONTROL*

1) *Position the PHANTOM on the PATIENT SUPPORT and assure that it overlaps the area of the AEC sensor.*
2) *For settings follow the INSTRUCTIONS FOR USE.*

ee) *Compliance criteria*

Compliance is achieved if:

No measured value of optical density differs by more than ±0,15 from the mean value of all exposures taken with combinations of X-RAY TUBE VOLTAGES and PHANTOM thickness from 2 cm to 6 cm as defined by the MANUFACTURER.

50.103 Accuracy of LOADING FACTORS

NOTE 50.101 and 50.102 contain requirements on operating data for mammographic X-RAY EQUIPMENT, as part of X-RAY GENERATORS, that are considered essential for protection against incorrect output.

The requirements of this subclause apply to the accuracy of all values of LOADING FACTORS, whether indicated, fixed or preselected when compared with MEASURED VALUES of the same LOADING FACTOR.

Compliance is determined by tests according to 50.104.

50.103.1 Accuracy and reproducibility of X-RAY TUBE VOLTAGE.

a) The X-RAY TUBE VOLTAGE shall be accurate within ±5 % of the INDICATED VALUE within the selectable range.
b) At the X-RAY TUBE VOLTAGE as defined by the MANUFACTURER, the coefficient of variation of reproducibility of the X-RAY TUBE VOLTAGE shall be equal to or less than 0,05.
c) the PERCENTAGE RIPPLE of output voltage (under the relevant conditions) of the HIGH-VOLTAGE GENERATOR shall not exceed 4.

50.103.2 Accuracy of X-RAY TUBE CURRENT

For operation of mammographic X-RAY EQUIPMENT in any specified combination with ACCESSORIES, the error of the value of the X-RAY TUBE CURRENT, in any combination of LOADING FACTORS, shall be not greater than 20 %.

50.103.3 Accuracy of IRRADIATION TIME

For operation of mammographic X-RAY EQUIPMENT in any specified combination with subassemblies, the error of the value of the IRRADIATION TIME, in any combination of LOADING FACTORS, shall be not greater than ± (10 % + 1 ms).

50.103.4 Accuracy of CURRENT TIME PRODUCT

For operation of mammographic X-RAY EQUIPMENT in any specified combination with sub-assemblies, the error of the value of the X-RAY TUBE CURRENT TIME PRODUCT, in any combination, shall be not greater than ± (10 % + 0,2 mAs).

This requirement also applies in cases when the CURRENT TIME PRODUCT is derived by calculation.

50.104 Test conditions

50.104.1 Accuracy and reproducibility of X-RAY TUBE VOLTAGE

Measurements shall be made at 3 settings of the X-RAY TUBE VOLTAGE: at 30 kV and at the lowest and highest selectable values. Each of these 3 settings shall be combined with the lowest, a medium and the highest selectable values of CURRENT TIME PRODUCT.

Complete each set of ten measurements within a time period of 1 h.

Calculate the coefficient of variation for each of the measurement series to verify compliance.

50.104.2 Accuracy of X-RAY TUBE CURRENT

One measurement shall be made at the lowest INDICATED VALUE of X-RAY TUBE CURRENT, the highest INDICATED VALUE of X-RAY TUBE VOLTAGE, and the shortest INDICATED VALUE of IRRADIATION TIME.

One measurement shall be made at the lowest INDICATED VALUE of X-RAY TUBE CURRENT, the highest INDICATED VALUE of X-RAY TUBE VOLTAGE, and an IRRADIATION TIME of approximately 0,1 s.

One measurement shall be made at the highest INDICATED VALUE of X-RAY TUBE CURRENT and the highest available X-RAY TUBE VOLTAGE for the tested X-RAY TUBE CURRENT and an IRRADIATION TIME of approximately 0,1 s.

50.104.3 Accuracy of IRRADIATION TIME

Determination of the IRRADIATION TIME

One measurement shall be made at the lowest INDICATED VALUE of IRRADIATION TIME and the highest INDICATED VALUE of X-RAY TUBE VOLTAGE and any INDICATED VALUE of X-RAY TUBE CURRENT.

One measurement shall be made at the lowest INDICATED VALUE of IRRADIATION TIME and the highest available electric power, P.

50.104.4 Accuracy of CURRENT TIME PRODUCT

One measurement shall be made at the lowest INDICATED VALUE of CURRENT TIME PRODUCT and the highest available X-RAY TUBE VOLTAGE.

One measurement shall be made at the highest INDICATED VALUE of CURRENT TIME PRODUCT and the lowest available X-RAY TUBE VOLTAGE.

50.105 Conditions for measuring AIR KERMA

50.105.1 Measuring arrangements

Arrange the X-RAY SOURCE ASSEMBLY, the DIAPHRAGM and the RADIATION DETECTOR for measurement under NARROW BEAM CONDITION.

50.105.2 RADIATION QUALITY for measurement of AIR KERMA

Ensure that the RADIATION QUALITY of the X-RAY BEAM emerging from the X-RAY SOURCE ASSEMBLY complies with applicable specified conditions for NORMAL USE. If no such conditions are specified, ensure that the TOTAL FILTRATION in the X-RAY SOURCE ASSEMBLY is such as to comply with the General Standard as applicable.

50.105.3 Tests for verifying reproducibility

Complete each set of ten measurements within a time period of 1 h.

Calculate the coefficient of variation for each of the measurement series and the average AIR KERMA for test setting C, to verify compliance according to 50.102.1.

The test geometry is as specified by the MANUFACTURER.

50.105.4 Tests for verifying linearity

Make ten measurements of AIR KERMA in one hour at the test settings C according to table 101.

Calculate the average value of AIR KERMA for the measurements series. Use these average values and those for test setting C from 50.105.3 to verify compliance according to the formula in 50.102.2).

The test geometry is as specified by the MANUFACTURER.

Table 101 – Tests for verifying reproducibility and linearity

Test setting	A	B	C
X-RAY TUBE VOLTAGE	Lowest	Highest	30 kV
X-RAY TUBE CURRENT or CURRENT TIME PRODUCT *)	Highest	Lowest	Giving 10 µGy – 100 µGy
*) As available with the settings defined in previous row.			

51 Protection against hazardous output

This clause of the General Standard applies.

SECTION 9: ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

The clauses and subclauses of this section of the General Standard apply.

SECTION 10: CONSTRUCTIONAL REQUIREMENTS

The clauses and subclauses of this section of the General Standard apply except as follows:

56 Components and general assembly

This clause of the General Standard applies except as follows:

56.7 Batteries

Addition:

56.7.101 Charging mode INTERLOCK

Every MOBILE EQUIPMENT having an incorporated battery charger shall be provided with means whereby powered movements and the generation of X-RADIATION by unauthorised persons can be prevented without preventing the charging of batteries.

NOTE An example of suitable means to comply with this requirement is the provisions of a key-operated switch arranged so that powered movements and the generation of X-RADIATION are possible only when the key is present, but battery charging is also possible in the absence of the key.

57 MAINS PARTS, components and layout

This clause of the General Standard applies except as follows:

57.10 CREEPAGE DISTANCES and AIR CLEARANCES

a) Values

Addition:

For PERMANENTLY INSTALLED X-RAY EQUIPMENT the values of table XVI of the General Standard for the insulation A-a1 and A-a2 of CLASS I EQUIPMENT apply up to a reference voltage of 660 V in a.c. r.m.s. or 800 V d.c.

For higher reference voltages the CREEPAGE DISTANCES and AIR CLEARANCES

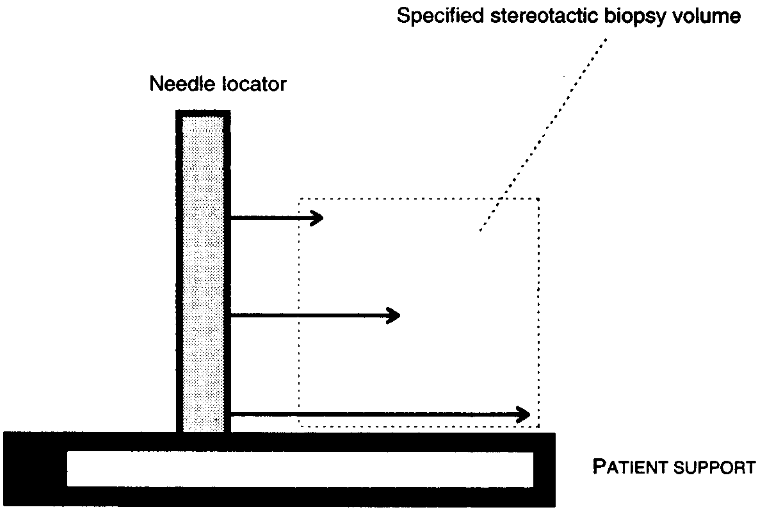
- shall be not less than those for 660 V a.c. r.m.s. and 800 V d.c. given in table XVI of the General Standard; and

- shall comply with the requirements according to 20.3 of the General Standard on dielectric strength for

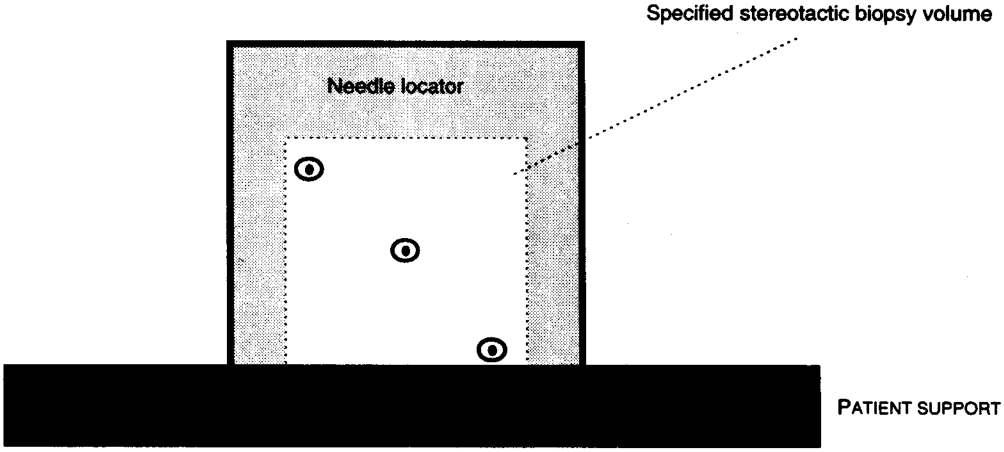
Reference voltages	Test voltages
660 V < $U \leq$ 1 000 V	2 U + 1 000 V
1 000 V < $U \leq$ 10 000 V	U + 2 000 V

The dielectric strength test shall be performed under environmental conditions as described in 20.4 of the General Standard.

NOTE For X-RAY EQUIPMENT installed with a fixed and permanently installed PROTECTIVE EARTH CONDUCTOR it is assumed that there is no risk with regard to the reliability of the protective earth connection. For the same reason there is a statement in 19.3 e) of the General Standard that under these circumstances a higher EARTH LEAKAGE CURRENT is admissible. This aligns with the statements on CREEPAGE DISTANCES and AIR CLEARANCES in IEC 60664-1.



a) Side view



b) Front view

Figure 101 – Example of a TEST DEVICE for MAMMOGRAPHIC STEREOTACTIC DEVICES

Annex AA
(normative)

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Annex BB
(informative)

Rationale for allowing full IRRADIATION of mammograms

The original text in 29.203.4 of IEC 60601-1-3 does not allow the X-RAY BEAM to extend beyond the edges of the IMAGE RECEPTION AREA, except at the edge adjacent to the chest wall. This is in accordance with good principles, recognizing that any RADIATION falling outside the film can produce no direct benefit to the PATIENT. However, this means that the necessary tolerance must always be in the direction of leaving margins on the film that are not irradiated. These transparent margins need to be covered at the time of viewing on a FILM ILLUMINATOR, in order to preserve satisfactory conditions for the viewer to be able to extract the diagnostic information in the film. This is becoming of greater importance, to the extent that the trend is towards the use of brighter illuminators and denser films, making the interference of the bright margins more intrusive.

While individual masking of the margins is possible when viewing small numbers of films, it is not a practical option under the conditions in which very large numbers of films are viewed, as in breast screening programmes. It is a fact that radiologists do, under these conditions, demand films without transparent margins. This is not a breach of the ALARA (As Low As Reasonably Achievable) principle, if it is responsibly judged that the resulting increased doses to PATIENTS (if any) are justified by the increased benefits to the individuals or to the population being screened.

The increased doses to PATIENTS resulting from allowing films to be completely irradiated are not likely to be significant. In mammography, the additional RADIATION near the edges concerned is not normally incident to the PATIENT and is stopped by the PRIMARY PROTECTIVE BARRIER (which, of course, needs to be dimensioned to allow for any increase in the permitted dimensions of the irradiated area). The insensitivity of PATIENT dose to the IRRADIATION of areas outside the region of interest in mammography is already recognized in the routine practice of irradiating the same area of the same-sized film for all PATIENTS, which in most cases substantially overlaps the actual region of interest. It is considered that the change in 29.203.4 of IEC 60601-1-3 in effect does no more than recognize existing professional practice and avoids a regulatory restriction that is not necessarily in the interests of PATIENTS. In no circumstances would it cause the mammographic X-RAY EQUIPMENT to become hazardous. For X-RAY EQUIPMENT used entirely in circumstances where the masking of films is practicable at the time of viewing, it is, of course, open to purchasers to specify an operational preference for EQUIPMENT that confines the X-RAY BEAM to a smaller area than the maximum permitted.

Annex CC
(normative)

Values of the series R'10 and R'20, ISO 497

The values, which shall be used according to 50.101.1 a) and 50.101.1 b) for marking and indication in fixed gradations of LOADING FACTORS having an essentially proportional relation to the amount of RADIATION received, shall be chosen as decimal multiples and submultiples from the following rounded values of the series R'10 and R'20:

Calculated values	R'10	R'20
1,0000	1,00	1,00
1,1220	–	1,10
1,2589	1,25	1,25
1,4125	–	1,40
1,5849	1,60	1,60
1,7783	–	1,80
1,9953	2,00	2,00
2,2387	–	2,20
2,5119	2,50	2,50
2,8184	–	2,80
3,1623	3,20	3,20
3,5481	–	3,60
3,9811	4,00	4,00
4,4668	–	4,50
5,0119	5,00	5,00
5,6234	–	5,60
6,3096	6,30	6,30
7,0795	–	7,10
7,9433	8,00	8,00
8,9125	–	9,00

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